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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/970,663	10/05/2001	Francis Blanche	03806.0517	2019

7590 10/02/2002

Finnegan, Henderson, Farabow,
Garrett & Dunner, L.L.P.
1300 I Street, N.W.
Washington, DC 20005-3315

EXAMINER

WHITEMAN, BRIAN A

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 10/02/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/970,663

Applicant(s)

BLANCHE ET AL.

Examiner

Brian Whiteman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-23 is/are pending in the application.
- 4a) Of the above claim(s) 19 and 20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 10-18 and 21-23 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Non-Final Rejection

Claims 10-18 and 21-23 are pending examination.

Election/Restrictions

Applicant's election with traverse of the species polymer in claim 16 in Paper No. 7 is acknowledged. The traversal is on the ground(s) that the office has not shown there would be no serious burden to examine all of the claimed species. This is not found persuasive because the species set forth in claim 16 do not overlap with each and each species would require a different literature search. Thus, it would be an undue burden on the examiner to search all the species listed in claim 16.

The requirement is still deemed proper and is therefore made FINAL.

Claims 19 and 20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a non-elected species, there being no allowable generic or linking claim.

Applicant timely traversed the restriction (election) requirement in Paper No. 7.

Priority

MPEP 202.01. states, "Except for a continued prosecution application filed under § 1.53(d), any non-provisional application claiming the benefit of one or more prior filed co-pending non-provisional applications or international applications designating the United States of America must contain a reference to each such prior application, identifying it by application number (consisting of the series code and serial number) or international application number and international filing date and indicating the relationship of the applications. This reference must be submitted during the pendency of the application, and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. This time period is not extendable. Unless the reference required by this paragraph is included in an application data sheet (§ 1.76), the specification must contain or be amended to contain such reference in the first sentence following the title. If the application claims the benefit of an international application, the first sentence of the specification must include an

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indication of whether the international application was published under PCT Article 21(2) in English (regardless of whether benefit for such application is claimed in the application data sheet). The request for a continued prosecution application under § 1.53(d) is the specific reference required by 35 U.S.C. 120 to the prior application. The identification of an application by application number under this section is the specific reference required by 35 U.S.C. 120 to every application assigned that application number. Cross-references to other related applications may be made when appropriate (see § 1.14). Except as provided in paragraph (a)(3) of this section, the failure to timely submit the reference required by 35 U.S.C. 120 and this paragraph is considered a waiver of any benefit under 35 U.S.C. 120, 121, or 365(c) to such prior application."

The specification is object to because in view of MPEP 202.01 the first sentence of the specification must include an indication of whether the international application was published under PCT Article 21(2) in English (regardless of whether benefit for such application is claimed in the application data sheet).

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 10, 11, 12, 13, 14, 15, 16, 17, 18, 21, 22, and 23 are rejected under 35

103(a) as being unpatentable over Wu et al. (US 2002/0031527, effective filing date 11/16/98) taken with (Sene et al. US Patent No. 6,451,256). Wu teaches a method for the preparation of a long-term storage stable adenovirus liquid formulation, comprising the steps of provides an adenovirus and combining said adenovirus with a solution comprising a buffer and a polyol (glycerol), whereby said adenovirus liquid formulation retains high infectivity (page 29). The buffer used for preparing the freeze-dried adenovirus formulation is Tri-HCl (page 3). Wu further teaches a method for the preparation of a long-term, storage stable adenovirus formulation, comprising the steps of providing adenovirus with a solution comprising a buffer, a

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bulking agent, a cryoprotectant and a lyoprotectant; and lyophilizing the solution, whereby lyophilization of the solution produces a freeze-dried cake of the adenovirus formulations that retains high infectivity and low residual moisture (page 2). The list of bulking agents, cryoprotectant and lyoprotectant are on pages 2-3. The composition for preserving adenoviral particles taught by Wu does not have added divalent metal cations or alkali metal cations. Buffering agents and other types of pH control can also be added simultaneously in order to provide for maximum buffering capacity for the adenovirus formulation. For example, pH changes that deviate from physiological conditions often result in irreversible aggregation of proteins (Wetzel, 1992) and viral capsids (Misselwitz et al., 1995) due to complete or partial denaturation of the protein. Thus, buffering agents are particularly important for virus preparations that aggregate or denature at sub-optimal pH ranges. However, Wu does not teach specifically teach a composition comprising adenovirus particles and a buffer solution that maintains the pH of said composition between 8.0 and 9.6 and glycerol.

However, at the time the invention was made, Sene teaches that a Tris buffer solution for preserving recombinant virus particles in frozen or liquid form (abstract). Sene teaches that the infectious viruses gain stability when the aqueous solution used has a basic pH between 8 and 9, preferably 8.5 (column 3). The pH of the buffer is about 8 to 9, preferably 8.5 (column 3-4 and 6-12).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the inventions was made to combine the work of Wu taken with Sene to produce comprising adenovirus particles, glycerol, and a buffer with a pH of 8-9. One of ordinary skill in the art

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would have been motivated to use the buffer at in the specific pH range taught by Sene because of the gain in stability of the viruses when the solution used has a basic pH.

Therefore the invention as a whole would have been *prima facie* obvious to one ordinary skill in the art at the time the invention was made.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kay Pinkney whose telephone number is (703) 305-3553.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (703) 305-0775. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's mentor, primary examiner, Dave Nguyen can be reached at (703) 305-2024.

If attempts to reach the primary examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader, SPE - Art Unit 1635, can be reached at (703) 308-0447.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

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Brian Whiteman

Patent Examiner, Group 1635

9/30/02

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DAVE T. NGUYEN
PRIMARY EXAMINER